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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,499	08/27/2001	Namita Surolia	2006443-0002 (IN99/00026)	8616

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
10/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No.	Applicant(s)	
	09/763,499	SUROLIA, NAMITA	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-59 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-59 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 11, 2007 has been entered.

Claims 54-59 and 63 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 54 and 59 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waller et al. (U) in view of Heath et al. (V).

Waller et al. teach that fatty acid biosynthesis is potentially an excellent target for therapeutics directed against malaria and specifically, *Plasmodium falciparum* (see abstract). Waller et al. teach that there are two types of fatty acid biosynthesis, type I is found in the cytosol of animals and fungi and type II is widespread among bacteria. Further, *Plasmodium* fatty acid biosynthesis genes that have been characterized in this reference are of type II. Waller et al. employed the antibiotic thiolactomycin, which is a selective inhibitor of type II fatty acid biosynthesis. When the effect of thiolactomycin was studied on the malaria parasite *Plasmodium falciparum* it demonstrated Thiolactomycin **inhibition of malaria**, thus providing additional supporting evidence for a type II fatty acid biosynthetic pathway in apicoplasts (an organelle in the Plasmodium organism9see) (page 12356, column 2).

Waller et al. does not teach triclosan.

Heath et al. triclosan and other 2-hydroxydiphenyl ethers directly inhibit fatty acid synthesis at FabI (enoyl-acyl carrier protein reductase) (see abstract and page 11110, column 2). Triclosan permeabilizes the bacterial envelope and FabI is a specific intracellular target for Triclosan (page 1114, column 1). Heath et al. further teach that the importance of fatty acid biosynthesis to cell growth and function makes this pathway an attractive target for development of antibacterial agents.

Heath et al. does not teach the treatment of infections by Plasmodium falciparum.

Waller et al. teach that Plasmodium falciparum is vulnerable to agents that inhibit fatty acid synthesis and specifically disclose that thiolactomycin is a specific agent that inhibits fatty acid synthesis. Heath et al. teach that triclosan as well as thiolactomycin, is a broad spectrum antibiotic that inhibits fatty acid synthesis. One of ordinary skill in the art could have substituted the thiolactomycin of Waller et al. for the triclosan of Heath et al. for the predictable result of inhibiting fatty acid synthesis.

It would have been prima facie obvious to substitute one inhibitor of fatty acid synthesis for the other for the treatment of a subject infected with malaria stemming from Plasmodium falciparum. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.

Claims 55 and 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waller et al. (U and Heath et al. (V). as applied to claims 54, 59 and 63 above, and further in view of Raether et al. U.S. Patent No. 4,260,615.

Raether et al. teach an antimalarial composition comprising inter alia chloroquine (column 1) and further recite that repeated use of antimalarials such as chloroquine induce resistance in Plasmodium falciparum (column 1, lines 8-13). Raether et al. teach the combination of chloroquine with other antimalarials.

Waller et al. teach that Plasmodium falciparum is vulnerable to agents that inhibit fatty acid synthesis and specifically disclose that thiolactomycin is a specific agent that inhibits fatty acid synthesis. Heath et al. teach that triclosan as well as thiolactomycin is a broad spectrum antibiotic that inhibits fatty acid synthesis. One of ordinary skill in

the art could have substituted the thiolactomycin of Waller et al. for the triclosan of Heath et al. for the predictable result of inhibiting fatty acid synthesis.

Waller and Heath do not teach the combination of triclosan with other antimalarial agents.

As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waller et al. (U and Heath et al. (V). as applied to claims 54, 59 and 63 above, and further in view of Dettmar et al. U.S. Patent No 5,286,492 and Remington's Pharmaceutical Sciences, 1975, (W)

Waller et al. teach that Plasmodium falciparum is vulnerable to agents that inhibit fatty acid synthesis and specifically disclose that thiolactomycin is a specific agent that inhibits fatty acid synthesis. Heath et al. teach that triclosan as well as thiolactomycin is a broad spectrum antibiotic that inhibits fatty acid synthesis. One of ordinary skill in the art could have substituted the thiolactomycin of Waller et al. for the triclosan of Heath et al. for the predictable result of inhibiting fatty acid synthesis.

It does not teach parenteral (by injection) administration of triclosan and it does not teach the dosage amount.

Dettmar et al. teach administration of triclosan in doses of from 1 to 200 mg administered by oral route (claim 1). Dettmar et al. does not teach treatment of malaria and it does not teach the exact dosage range of 0.03 mg/kg to 100 mg/kg, however, one having ordinary skill in the art could readily extrapolate the dosage. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infection would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to have used the recited dosages of triclosan.

Regarding administration by injection, Remington's Pharmaceutical Sciences (U) teach that when compared to other dosage forms, injections possess select advantages such as immediate physiological action, modification of the formula or administration by another route to slow onset and prolong the action of the drug, the drug is more readily controlled and avoids the irregularities of intestinal absorption (page 1461, column 2, last paragraph). One having ordinary skill in the pharmaceutical arts could readily formulate triclosan into an injectable composition with the benefits detailed above.

It would have been obvious to one of ordinary skill in the art to employ triclosan in a parenteral dosage form motivated by the recited advantages above.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

September 20, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614